REMARKS

This Amendment responds to the Office Action dated July 11, 2007 in which the Examiner rejected claims 1, 3-5 and 7-20 under 35 U.S.C. §103.

Claim 1 claims an injection needle and claim 4 claims a liquid introducing instrument comprising an injection needle. The injection needle comprises a puncture section having a needle point capable of piercing a living body, a proximal end section having outside and inside diameters greater than the puncture section, and a tapered section interconnecting the puncture section and the proximal end section. The proximal end section possesses an outside diameter ranging from 0.35 mm to 1 mm, and the puncture section possesses an outside diameter ranging from 0.1 mm to 0.5 mm. The length from the puncture section to the tapered section ranges from 0.2 mm to 15 mm. The tapered section possesses an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle. In addition, the tapered section provides puncture resistance smaller than the puncture section.

To better define aspects of the injection needle and the liquid introducing instrument in a manner that further distinguish over the disclosures in the cited references, Claims 1 and 4 are amended to recite that the length of the tapered section ranges from 1.5 mm to 10 mm, and the puncture resistance of the puncture section is 7 gf or less.

Claims 1, 3, 4, 5, 19 and 20 were rejected under 35 U.S.C. §103 as being unpatentable over *Gross* (U.S. Patent. 4,781,691) in view of *Melker* (U.S. Patent 5,242,410). This rejection is respectfully traversed.

As explained previously, *Gross* discloses a needle assembly for performing a spinal anesthesia procedure. The needle assembly includes a needle 10 having a hollow proximal hub 12, a first tubular portion 14 of uniform diameter extending distally from and connected to the hub 12, and tubular end portion 16 located distal of the first tubular portion 14 and having a smaller uniform diameter than the first tubular portion 14. In addition, a tapered intermediate portion 18 is positioned between the first tubular portion 14 and the second tubular portion 16.

As shown in FIGS. 2 and 3 of *Gross*, the disclosed needle assembly also includes a stylet 22 in the form of an elongated rod 24 that is positioned inside the needle 10 and extends through the hub 12, the first tubular portion 14, the intermediate portion 18, and the second tubular portion 16 of the needle 10. The stylet 22 has a beveled tip 26 which is flush with the beveled tip 20 of the needle 10. As shown in FIG. 9, the rod 24 is configured with an enlarged first portion 60 possessing an outer diameter approximately equal to the inner diameter of the first needle portion 14, and a smaller distal portion 62 possessing an outer diameter approximately equal to the inner diameter of the second needle portion 16. *Gross* states in column 4, lines 9-26 that the stylet 22 is needed to provide additional strength to the needle 10 during use.

On point that is apparent from a careful reading of the disclosure in *Gross* is that *Gross* is not at all concerned about the configuration of the intermediate tapered portion 18, and certainly does not describe that the intermediate tapered portion 18 should be configured in a way that exhibits a smaller puncture resistance than the puncture section at which the beveled tip 20 is provided.

The present application describes why it is desirable to configure the needle so that the puncture resistance of the tapered section is less than that of the puncture section. There are various factors which have an affect on the puncture resistance of the tapered section relative to the puncture section, including the angle formed by the outer profile of the tapered section relative to a line parallel to the central axis of the needle, and the length of the tapered section. It is noted in this regard that Fig. 8 of the present application illustrates a rise in the load or puncture resistance as the needle is further advanced, thus indicating that the length of the tapered section has a bearing on the puncture resistance of the tapered section being less than that of the puncture section. In addition to currently reciting the angle formed by the outer profile at the tapered section, Claims 1 and 4 are amended to recite the length of the tapered section and to recite that the puncture section possesses a puncture resistance of 7 gf or less.

With respect to *Gross*, in addition to not disclosing that the intermediate tapered portion 18 should possess an outer profile forming an angle ranging from .5 degrees to 1 degree and 20 minutes, *Gross* does not disclose or suggest that the intermediate tapered portion 18 should possess a length ranging from 1.5 mm to 10 mm, and that the puncture section should possess a puncture resistance of 7 gf or less.

The puncture resistance of 7 gf or less as claimed here is quite relevant when considered in the context of the needle assembly described in *Gross*. As discussed above, the needle assembly described in *Gross* includes the stylet 22. This stylet 22 is a necessary part of the overall needle assembly because, as *Gross* notes, the stylet imparts necessary strength to the needle 10, a requirement as the needle is

advanced through the dura mater and into the subarachnoid space below the spinal cord. However, by virtue of the presence of the stylet 22 which is flush with the needle beveled tip 20 of the needle 10, the needle necessarily has a large puncture resistance, much larger than the puncture resistance of 7 gf or less set forth in Claims 1 and 4.

The observation in the Official Action that Gross inherently discloses a puncture section having a puncture resistance of 7 gf or less is not supported by the record. First, the Official Action has not established that all parameters which contribute to the puncture resistance are identical in both *Gross* and the needle at issue here. The only point the Official has established is that there is a slight overlap in *Gross's* disclosure of an outer diameter of 0.457 mm-0.635 mm (0.018 inches to 0.025 inches) for the second tubular portion 16 and the claimed outer diameter range of 0.1 mm to 0.5 mm for the puncture section. This does not establish that one of ordinary skill in the art would recognize that *Gross* inherently discloses a puncture resistance of 7 gf or less, particularly as Gross does not even mention that puncture resistance is of concern in configuring the disclosed needle assembly.

As discussed in MPEP § 2112 (IV), that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill. Inherency, may not be established by probabilities or possibilities. *In re Robertson*, 169 F.3d

743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). It has not been established here that one of ordinary skill in the art would recognize that the puncture section of *Gross's* needle inherently possesses a puncture resistance of 7 gf or less.

The Official Action relies upon Melker for its disclosure of a particular taper. This reliance is misplaced. *Melker* describes a wireless high flow sheath introducer for intravascular access. The introducer includes a dilator 4 which is placed over the needle 1 at the initial stage of insertion into a vessel. *Melker* states that the degree of taper for the dilator 4 from its distal end 5 to the transition point 6 is preferably in the range of about 1.26° to about 5.18° (a slope of about 0.022 to about 0.09) for a straight-sided dilator 4.

Thus, as explained in earlier response, *Melker's* disclosure pertains to the taper on a dilator, not the taper on a needle. Indeed, *Melker* discloses that the dilator 4 is used in connection with a needle 1, yet nowhere states that the taper on the dilator is also applicable to the needle.

The Official Action comments that *Melker's* disclosure specifically related to a dilator is applicable to a needle because both needles and dilators are elongate tubes that pass through the skin into the body. That it is possible to broadly characterize these two significantly different devices in such a manner does not support the rejection. In *Melker*, there is a readily apparent reason why the outer surface of the dilator is provided with the disclosed taper. And that reasoning does not apply to needles.

In use, *Melker's* dilator 4 is placed over the needle 1 and the high flow intravascular sheath 8 is placed over the dilator 4. The needle 1 extends a short distance beyond the distal end of the dilator and is used to puncture the skin and

enter the vessel. Once access the vessel is achieved, the dilator 4 enters the vessel. With the dilator 4 placed over the needle 1, it necessarily follows that the smallest possible outer diameter for the dilator is dictated by the outer diameter of the needle (and the outer diameter of the high flow intravascular sheath 8 to which the dilator outer surface transitions). In this regard, *Melker* states that the outer diameter of the needle is 1.07 mm (0.042 inches) which is more than two times larger than the upper end of the outer diameter range of the puncture section recited in Claims 1 and 4. *Melker* further states the outer diameter of the distal end 5 of the dilator (i.e., the smaller end) is 1.27 mm (0.05 inches) and widens to an outer diameter of between about 2.0 mm (0.79 inches) and 3.0 mm (0.118 inches). Thus, in *Melker*, once the sharpened distal end 2 of the needle 1 pierces the vessel, the opening in the vessel encounters the relatively large 1.27 mm outer diameter distal end of the dilator 4. Since the introduction of the dilator 4 into the vessel begins with such a large outer diameter, it is not surprising that *Melker* describes a degree of taper for the dilator 4 in the range of about 1.26° to about 5.18°. Such a taper is necessary to allow the quite large outer diameter dilator 4 to be advanced to a point allowing the even larger outer diameter high flow intravascular sheath 8 (outer diameter of 3.0+ mm) to be introduced into the vessel.

However, *Melker's* disclosure of a dilator having a taper in the range of about 1.26° to about 5.18° to permit the opening in the vessel to slowly accommodate the quite large outer diameter dilator as the dilator is advanced and reciprocated in the vessel is not a disclosure that one should use the same taper in a needle where similar concerns do not exist. Skilled artisans recognize that dilators are, almost by definition, intended to dilate or expand the vessel to achieve a relatively large size

opening to permit the introduction of an even larger instrument -- for example the 3.0+ mm outer diameter high flow intravascular sheath 8 described in *Melker*. To an ordinarily skilled artisan, this is not a teaching that one should use this same taper on other medical instruments such as needles which are not used for the same purpose and do not raise the same concerns.

The Official Action observes that the present application mentions a range for the outer profile angle that is not limited to the claimed angle range set forth in Claims 1 and 4. From this, the Official Action concludes that the claimed range is not "critical" and so patentability is denied. The basis for this position is not apparent. There is no requirement that only those features which a specification identifies as "critical" can serve as a basis for non-obviousness arguments. Here, the specification describes that the angle formed by the outer profile contributes, together with other aspects of the needle, in producing certain desirable results. That the specification here describes the possibility of an angle slightly outside the more preferred and claimed range in no way diminishes the relevance of this aspect of the claimed needle to the overall advantages achieved by the claimed needle.

As mentioned above, Claims 1 and 4 are amended to define that the length of the tapered section ranges from 1.5 mm to 10 mm. This, together with other aspects of the needle such as the claimed angle formed by the outer profile of the tapered section, contributes to achieving a puncture resistance of the tapered section that is less than that of the puncture section. Neither *Gross* nor *Melker* discloses a tapered section having a length ranging from 1.5 mm to 10 mm. Noting Melker's disclosure that the length of the dilator 4 is between 0.75 inches and 1.0 inches, and noting also that the tapering portion begins a short distance back from

the distal end, the tapering portion of *Melker's* dilator 4 has a length just short of 19 mm - 25 mm. Even at the lower end of this disclosed range, the length of the tapering portion of *Melker's* dilator is almost twice as long as claimed.

As a final point, independent Claims 1 and 4 recite that the puncture resistance of the tapered section is less than the puncture resistance of the puncture section. Neither Gross nor *Melker* discloses this claimed relationship. Indeed, neither reference is at all concerned about puncture resistance or the relative puncture resistance of a tapered section and a puncture section. In addition, the two references lack disclosure of the length of a tapered section which is a factor that contributes to achieving the claimed puncture resistance relationship. It is also significant to note in this regard that *Melker* is relied upon for its disclosure of a taper angle on a dilator. Even if it is assumed that an ordinarily skilled artisan would find this disclosure relevant to a needle such as described in *Gross*, there exists no teaching of incorporating that disclosed taper into *Gross's* needle in a way that would necessarily result in the puncture resistance of the tapered section being less than the puncture resistance of the puncture section as claimed.

For at least the foregoing reasons, withdrawal of the rejection of independent Claims 1 and 4 is respectfully requested.

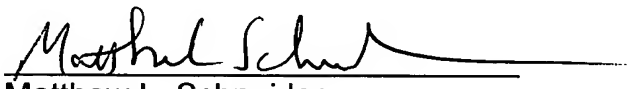
The dependent claims are allowable at least by virtue of their dependence upon allowable independent Claims 1 and 4. Thus, a discussion of the additional distinguishing features recited in the dependent claims is not set forth at this time.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: October 11, 2007

By: 

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